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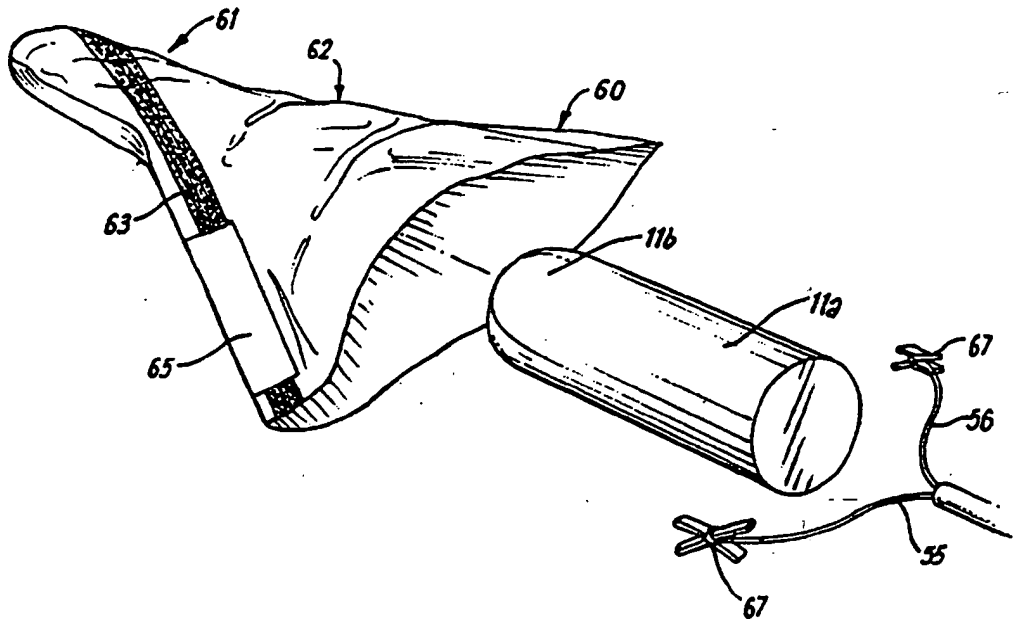

(57) Abstract

An electrode assembly for use in muscle stimulation e.g. by insertion into a vagina or rectum comprises an electrically non-conductive support (11a) which can be inserted into portion (61) of flexible bag (60) having helical electric contacts (63, 64), a non-conducting sheet (62) and connectable by leads (55, 56) to a control unit for supplying electric pulses in accordance with a treatment programme. The helical disposition of electrodes generally avoids ineffective positioning of the device.

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ELECTRICAL TREATMENT APPARATUS

THIS INVENTION relates to electrical treatment apparatus.

According to this invention an electrode assembly for use in muscular stimulation is shaped for insertion in a body orifice and comprises two spaced electrodes on an external surface characterised in that each electrode extends both axially and circumferentially.

The electrodes may be on an insulating substrate.

The or each electrode is present through the length of the surface and may for example be wound in a helix.

The electrodes may be formed on a flexible sheet mounted on a support, which support can be separate from the sheet.

The invention includes an electrode device for use in an assembly as above and comprising a flexible sheet carrying the electrodes.

The support may comprise electric supply contacts engaging the electrodes. There may be a portion disposed to limit insertion into the body orifice.

The invention may be performed in various ways and some specific embodiments with possible modifications will now be described by way of example only with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a vaginal electrode assembly;

Fig. 2 is a view of Fig. 1 with part folded open;

Fig. 3 is a perspective view of a modification;

Fig. 4 is a perspective view of another electrode;

Fig. 5 is an end view of Fig. 4;

Fig. 6 is a view of dissembled parts of a further electrode of Fig. 6;

Fig. 7 is a view of the assembled electrode of Fig. 6;

Figs. 8, 9, 10 show use of the electrode;

Fig. 11 shows a control unit;

and Figs 12-14 show another arrangement.

It is known to treat conditions of stress incontinence, detrussor instability and anorectal problems such as anorectal incontinence by neuromuscular stimulation.

A clearer understanding of the normal mechanism of control which exists between nerves and muscle makes it possible to take over control of muscle metabolism by the appropriate application of precise electronic signals. It has been shown that nerves control muscle by transmitting a neurological code. This code occurs in two frequency bands according to the type of muscle fibre required. Postural fibres require a tonic feeding at the rate of 10 pulses per second. If given for periods of one hour or more per day, it is possible to maintain all their essential characteristics. This treatment

for muscles can act as a life support system until normal function can be resumed. Muscles treated in this way are able to preserve bulk, capillary bed density, and their essential ability to utilise oxygen.

The second frequency band occurs at 30pps, and feeds information to the fast contracting muscle fibres which give power to a movement. This feeding occurs naturally in a phasic way, and therefore treatment protocols to promote these fibres are given for shorter periods of time.

This physiological approach to neuromuscular stimulation also requires pulses, which are shaped like the naturally occurring nerve signals and have very brief pulse widths. By mimicking nature as accurately as possible, electrical stimulation has been used for prolonged periods, when required, without causing any side effects.

Neuromuscular stimulation may be used in patients with anorectal incontinence to increase the postural tone of the pelvic floor musculature and to strengthen the internal and external anal sphincter. The use of an internal electrode also increases sensory awareness of rectal distension, thus helping the patient to differentiate between flatus, liquid and solid stool. Reflex activity increases the colonic shuttle reflex and leads to the formation of solid stool form; most of these patients are only incontinent of liquid or soft form stool.

In genuine stress incontinence slight leakage of urine occurs on coughing, laughing, sneezing etc. The volume of urine leaked is less than a teaspoonful and is not associated with detrussor instability. The pelvic floor muscles have lost postural tone and the

fast twitch fibres, although present, are not in a suitable position effectively to reinforce the sphincter contraction during sudden rises in intra-abdominal pressure.

The electrodes are placed in the vagina or rectum and electrical pulses are supplied from a control unit in accordance with a treatment programme.

For example treatment programme I may be of 1 hour per day for 12 weeks, the programme I being pulses of 200μS width, 2 seconds on 2 seconds off at a frequency of 10 pulses per second.

This can be succeeded by treatment programme II in which the muscles are voluntarily contracted by the patient during stimulation from the electrodes. For example treatment programme II may be for 1 minute per day rising to 10 minutes per day with a pulse width of 200μS, for 4 seconds on 4 seconds off at a frequency of 35 pulses per second.

Other treatment programmes are possible as advised.

The present invention provides an electrode device for use in neuromuscular stimulation.

Referring to Figs. 1, 2, an electrode assembly 10 comprises an electrically insulating and medically inert substrate or support 11 which carries an electrode portion 12 in the form of a helix.

The substrate 11 may for example be of foamed polystyrene, so-called pod grade, and is thus light in weight. Although not rigid, the substrate or support 11 is effectively of fixed shape with no tendency to expand.

The substrate 11 has a domed inner end 13, a tapered body 14, and a locating enlarged outer end 15, the portions 13, 15

providing opposed shoulders 13a, 15a.

An axial recess 16 in the substrate receives electric conductors 17, 18 respectively connected to flat conducting elements 17a, 18a.

An electrically insulating sheet 19, for example of thin flexible plastics-coated cardboard, is cut to size and in its outer surface 20 has secured by adhesive two strip electrodes 21, 22 which are generally helically wound and include inner parts 21a, which, when the sheet 19 is wrapped round the body 14, respectively contact elements 17a, 18a so that electrodes 21, 22 can receive electrical pulses from a control device 23 Fig. 9 which can be operated by a user. The radially inner surface of the sheet 19 can be adhered to the body 14. The shoulders 13a, 15a help to locate the sheet 19. The electrodes 21, 22 may for example be of aluminium. It will be understood that a user may in some cases carry the control unit 23 about with them. Programme I may be used to treat detrussor instability.

The assembly 10 in use is inserted into the vagina 30 Figs. 8, 10. Indicated are bladder 31, urethra 32, coccyx 33, uterus 34, pelvic floor or levator ani muscles 35, rectum 36.

The enlarged outer end 15 enables shoulder 15a to locate the assembly 10 by engagement with the body adjacent the entrance to the vagina 30. The electrodes 21, 22 contact the vaginal wall surface.

The disposition of electrodes 21, 22 on body 14 is such that each electrode 21, 22 is present at each axial position of the body 14 irrespective of the axial or rotational position of the body 14

into the vagina.

The end portions 13, 15 can take different shapes (Figs. 3, 4, 5) and body 14 can be of uniform cross-section (Fig. 4).

In Figs. 6, 7 the assembly 10 is formed e.g. by casting two parts 40, 41 with grooves 42, for receipt of conductors 17, 18, and projections 43 and recesses 44 which can co-operate with a snap action when the parts are brought together Fig. 7.

The assembly 10 can be used for muscle stimulation also in the rectum, see Fig. 9.

The plug or assembly 10 is fitted with a small flange 15 which ensures that the treatment areas of the electrodes are placed on the relevant levator ani muscles.

The helical winding of electrodes 21, 22 gives even charge density in any position. However, the flange also ensures orientation.

The light bright nature of the plug in addition to the above design features enables the woman to walk around and generally take part in most day to day activities whilst receiving treatment.

Pulsed electric supply to the electrodes 21, 22 can be from control unit 23 Fig. 11 which may be battery driven, with on/off switch 50, LED 51 to indicate "on", a switch 52 to select programme I or II; manually operable buttons 53, 54 to increase or decrease the amplitude or intensity of the pulses, and output leads 55, 56 for removable attachment respectively to ends of fly leads 17, 18 themselves respectively secured at their other ends to the electrodes 17a, 18a. The fly leads 17, 18 can be secured to the electrodes during or after securement of the electrodes to the blank 19.

After a single use, the device 10 can be disposed of, or it can be re-used. The substrate is electrically non-conductive.

Figs. 12, 13, 14 illustrate another arrangement in which the substrate 11a is a plastics support e.g. blow moulded, generally cylindrical with a rounded end 11b. The electrodes are formed on a separate flexible sheath 60 of electrically insulating material e.g. cellulose or polypropylene. The sheath 60 is in the form of a container having a generally projecting tubular portion 61 and a flared portion 62. In use Fig. 14, the support 11a fills and thus stiffens the portion 61 into substantially a cylinder and the flared portion 62 assists (Fig. 14) in locating the device 10 axially. As can be seen in Fig. 14, the end of support 11a can be flared to assist in correct axial positioning.

The electrodes 63, 64 are formed as coatings on the sheath 60 e.g. by sputtering and in part receive an outer electrically insulating coating 65 leaving a contact area 66 which can be engaged by clips 67 at the ends of leads 55, 56. The electrodes are generally helical in use in portion 61.

The support can be used with a succession of sheaths 60 which are disposed of after use.

It will be observed that each of the electrodes (one anode, one cathode) is present throughout the length of the body 14, 61 and effective muscle stimulation is thus obtained substantially irrespective of variation in axial position of the muscle 35 in relation to the body 14, 61 which results from vaginas of different size, and any need for rotational adjustment is partly or wholly removed having regard to the fact that muscle damage may be at any place around the vagina or rectum wall.

Preferably each electrode 21, 22; 63, 64 extends circumferentially substantially 180° to give a total of substantially 360° as viewed axially, but effective arrangements can have a greater or lesser circumferential extent.

Preferably the electrodes are uniform helices of equal width and of equal width to the angular helical gaps between the electrodes, as shown in Figs. 1, 7 so that a maximum area of muscle is stimulated, preferably all the surrounding wall.

The vaginal and rectum wall musculature has angularly spaced pudendal nerve networks whose positions can vary, possibly positioned on the left and right side of the orifice. The nerve networks are both motor and sensory. The circumferentially extending electrodes make it more likely that one or both nerve networks are stimulated without rotary repositioning of the device.

It will be understood that an electrode extending circumferentially contacts, and thus stimulates a greater area of muscle than an axial electrode of equal width for a given axial distance, and the greater area permits a lesser, and therefore more confortable, charge density for a given power input; and the helical configuration enables stimulation of a greater amount of axially extending muscles and circumferentially extending muscles because the electrodes and the gaps between have both axial and circumferential components at each axial position.

This is in contrast to an arrangement having a non-conductive support carrying two axially spaced annular conductive rings or an arrangement having a non-conductive support carrying two axially extending parallel conductors which are angularly spaced.

The vaginal or rectal orifice can change in cross-section with the posture of the individual and the circumferential configuration of electrodes and gaps reduces the possibility of a change in cross-section reducing the amount of muscle stimulation which would occur if the electrodes lost contact with the orifice musculature.

CLAIMS

1. An electrode assembly for use in muscular stimulation shaped for insertion in a body orifice and comprising two spaced electrodes (21, 22; 63, 64) on an external surface characterised in that each electrode (21, 22; 63, 64) extends both axially and circumferentially.

2. An electrode assembly as claimed in Claim 1, characterised in that each electrode (21, 22; 63, 64) is wound in a helix.

3. An electrode assembly as claimed in claim 2, in which the helix is uniform.

4. An electrode assembly as claimed in any of Claims 1 to 3, characterised in that the electrodes (21, 22; 63, 64) are formed on a flexible sheet (19; 60) mounted on a support (14; 11a).

5. An electrode assembly as claimed in Claim 4, in which the flexible sheet (19; 60) carries electrical contacts (66) exterior to the body orifice for connection to supply leads.

6. An electrode assembly as claimed in Claim 5, characterised in that the sheet (19; 60) is separable from the support (14; 11a).

7. An electrode assembly as claimed in Claim 4 or Claim 6, characterised in that the support (14) comprises electric supply contacts (17a, 18a) engaging the electrodes (21, 22).

8. An electrode assembly as claimed in any preceding claim, characterised by a portion (15, 62) disposed to limit insertion into the body orifice.

9. An electrode device for use in an assembly as claimed in

any preceding claim comprising a flexible sheet (19, 60) carrying the electrodes (21, 22; 63, 64).

10. An electrode device as claimed in Claim 9, in which the flexible sheet (19; 60) carries electrical contacts (66) exterior to the body orifice for connection to supply leads.

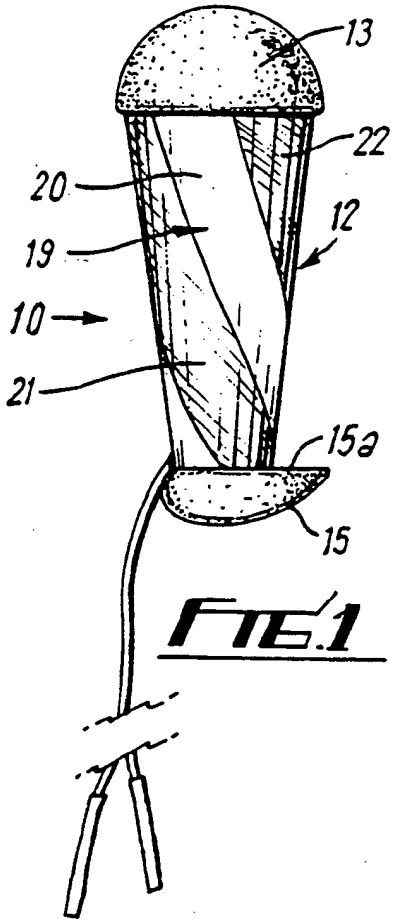

FIG.1

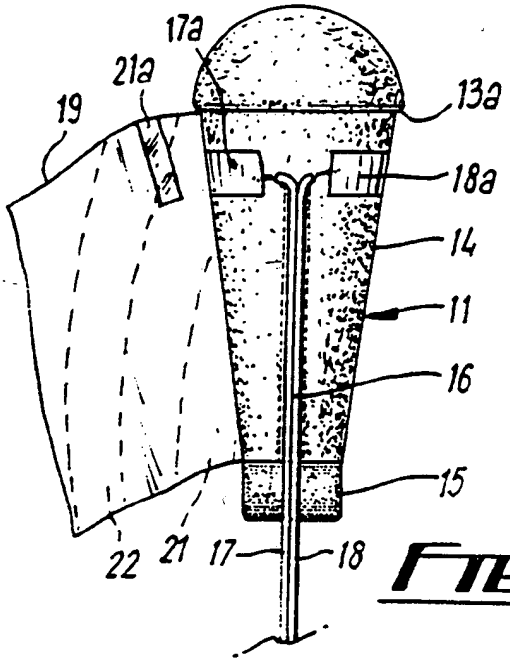

FIG.2

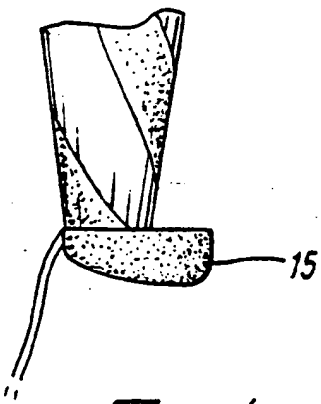

FIG.3

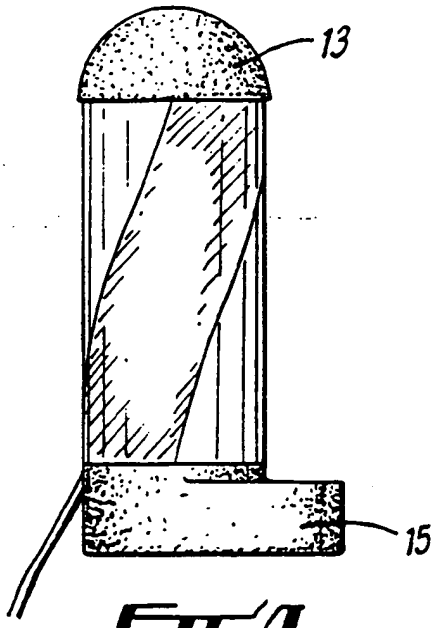

FIG.4

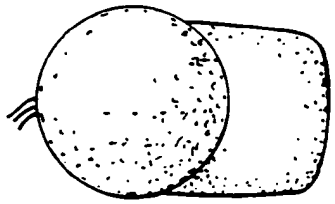

FIG.5

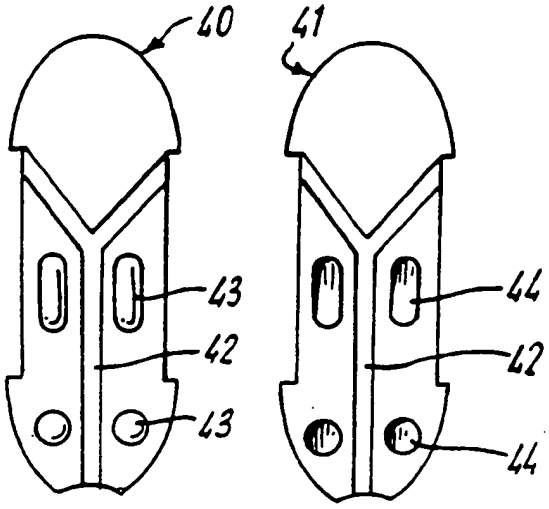

FIG.6

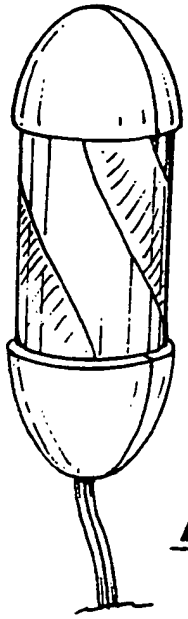

FIG.7

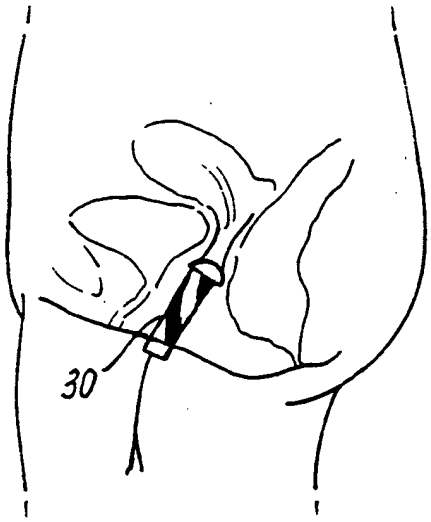

FIG. 8

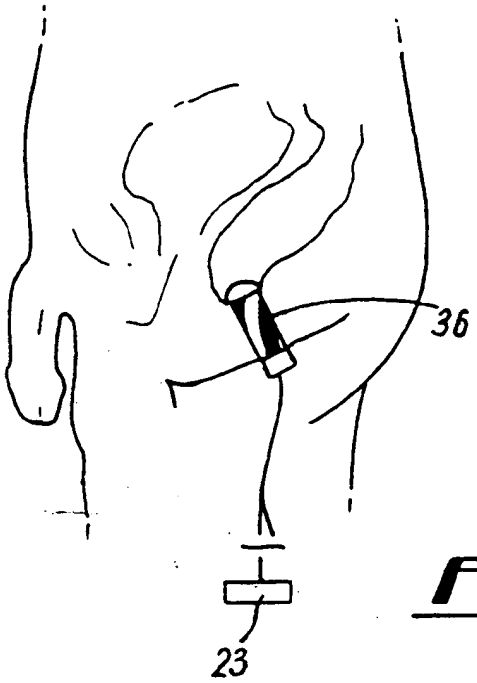

FIG. 9

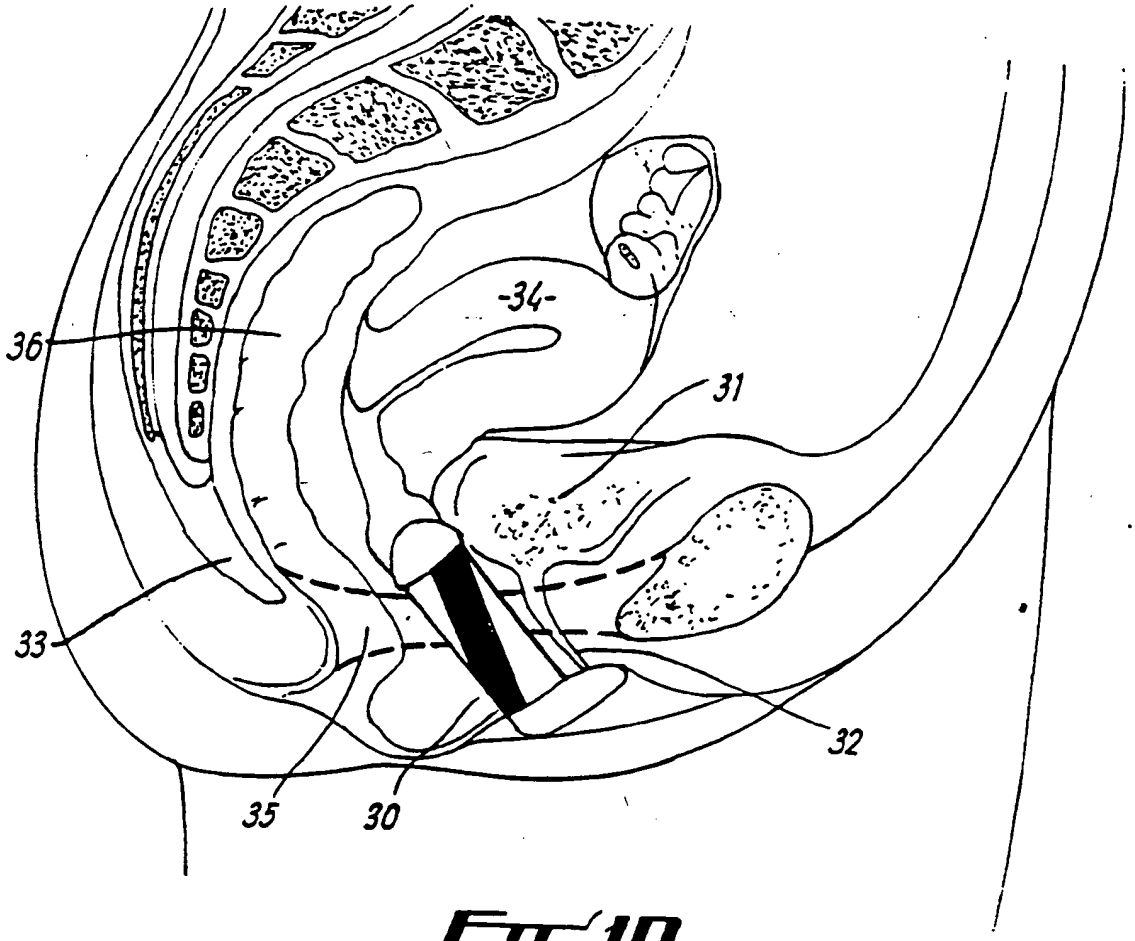

FIG.10

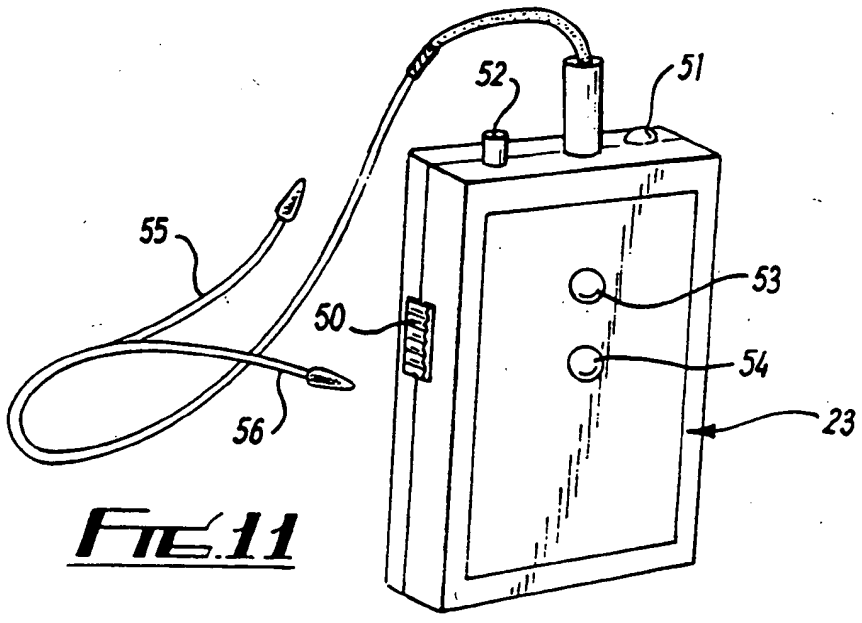

FIG.11

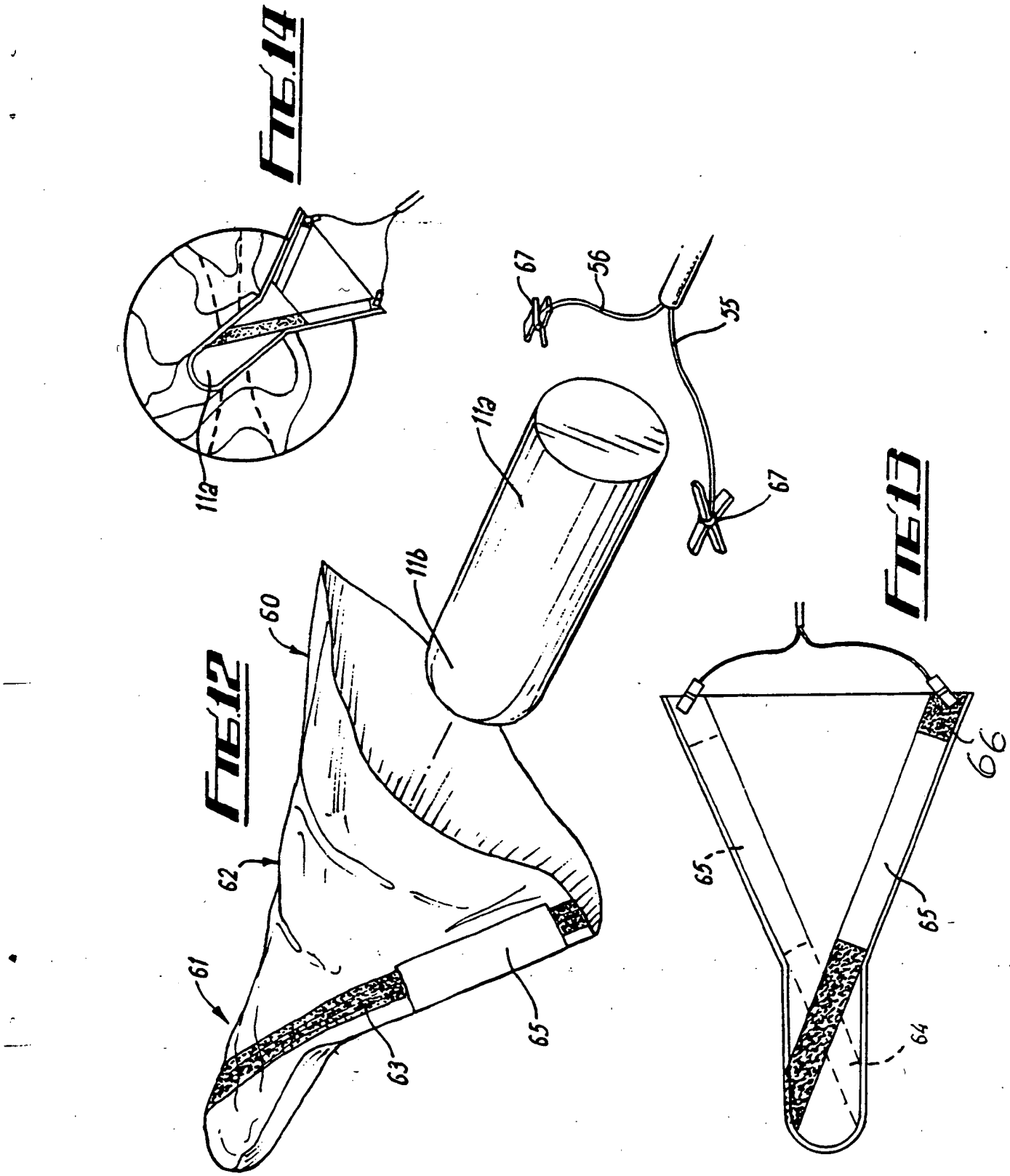

Fig.14

Fig.12

Fig.13

INTERNATIONAL SEARCH REPORT

Internationa pplication No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO-A-92 14510 (PEZ RENE) 3 September 1992 see page 3, line 27 - page 7, line 9; figures	1-3 5,8
A	EP-A-0 411 632 (EMPI INC) 6 February 1991 see page 2, column 2, line 44 - page 3, column 4, line 48; figures	1,4,5,7, 9,10
A	US-A-4 881 526 (JOHNSON MICHAEL T V ET AL) 21 November 1989 see column 3, line 57 - column 7, line 49; figures	1,8
A	GB-A-2 119 516 (PERRY JOHN DELBERT) 16 November 1983 see page 3, line 105 - page 5, line 8; figures	1

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7 August 1995	31.08.95

Name and mailing address of the ISA	Authorized officer
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Information on patent family members

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GB-A-2119516	16-11-83	NONE	